

CLAIMS:

1. A composition comprising (i) chitosan, a salt or derivative thereof or a salt of a derivative thereof, (ii) a polyol-phosphate or sugar-phosphate salt, (iii) a plasticizer, and (iv) a therapeutic agent.
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2. A composition according to claim 1 in the form of an aqueous solution or suspension.
- 10 3. A composition according to claim 1 or 2, which forms a gel at a temperature 30 °C or greater.
4. A composition according to claim 3, which forms a gel in 15 minutes or less at a temperature of from 30 to 40 °C.
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5. A composition according to claim 4, which forms a gel in 15 minutes or less at a temperature of from 35 to 37 °C.
6. A composition according to any one of the preceding claims, wherein the plasticizer is triethyl citrate.
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7. A composition as claimed in any one of the preceding claims, wherein the chitosan, salt or derivative thereof or salt of a derivative thereof has a molecular weight of 4000 Dalton or greater.
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8. A composition according to claim 7, wherein the chitosan, salt or derivative thereof or salt of a derivative thereof, has a molecular weight of from 50,000 to 300,000 Dalton.

9. A composition according to any one of the preceding claims,
comprising chitosan base or a chitosan derivative that has been formed
by bonding of acyl or alkyl groups with the hydroxyl groups of the
chitosan or a nitrate, phosphate, sulphate, citrate, hydrochloride,
5 glutamate, lactate or acetate salt of chitosan.
10. A composition according to any one of the preceding claims, wherein
the chitosan has a degree of deacetylation of 40 % or greater.
- 10 11. A composition according to claim 12, wherein the degree of
deacetylation is from 70 to 90 %.
12. A composition according to any of the preceding claims comprising
from 0.25 to 3.0 % w/v of chitosan, a salt or a derivative thereof or a
15 salt of a derivative thereof expressed as chitosan base.
13. A composition according to claim 12 comprising from 0.45 to 1.5
%w/v of chitosan, a salt or a derivative thereof or a salt of a derivative
thereof expressed as chitosan base.
- 20 14. A composition according to any one of the preceding claims, wherein
the therapeutic agent is present in solution or as a suspension.
- 15 15. A composition according to any one of the preceding claims, wherein
the polyol-phosphate salt is β -glycerophosphate disodium.

16. A composition according to any one of the preceding claims, wherein the polyol-phosphate or sugar-phosphate salt is present in an amount of from 0.25 to 3.0 % w/v.
- 5 17. A composition according to claim 16, wherein the polyol-phosphate or sugar-phosphate salt is present in an amount of from 0.75 to 2.0 % w/v.
18. A composition according to any one of the preceding claims
10 comprising from 0.05 to 5.0 % w/v of the plasticizer.
19. A composition as claimed in Claim 18 comprising from 0.2 to 1.0 % w/v of the plasticizer.
- 15 20. A composition according to any of the preceding claims additionally comprising ascorbic acid.
21. A composition according to claim 20 comprising from 0.01 to 0.2 % w/v ascorbic acid.
- 20 22. A composition according to any one of the preceding claims, wherein the therapeutic agent is a polar drug, a polypeptide, a gene or a gene construct.
- 25 23. A composition according to claim 22, wherein the therapeutic agent is insulin, calcitonin, leuprolide, luteinising hormone releasing hormone, growth hormone or a growth hormone releasing factor, naratriptan, sumatriptan, zolmitriptan, rizatriptan, eletriptan, frovatriptan, alnitidan, avitriptan, almotriptan, apomorphine, sildenafil, alprostadil,

diamorphine, hydromorphone, buprenorphine, fentanyl, oxycodone, codeine, morphine or morphine-6-glucuronide.

24. A drug delivery device suitable for delivery of a composition via one
5 or more of the nasal, vaginal, rectal, oral mucosal, ophthalmic or ocular routes or a dose cartridge for use with such a device loaded with a composition as defined in any one of the preceding claims.

25. A process for the preparation of the composition as defined in any one
10 of claims 1 to 23, which process comprises mixing a solution comprising chitosan or a salt or derivative thereof or a salt of a derivative thereof with a solution comprising a polyol-phosphate or sugar-phosphate salt.

15 26. The use of the combination of chitosan or a salt or derivative thereof or the salt of a derivative thereof, a polyol-phosphate or sugar-phosphate salt and a plasticizer in the manufacture of a medicament for use in the transport of a therapeutic agent across a mucosal surface in an animal.

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27. The use of the combination of chitosan or a salt or derivative thereof or the salt of a derivative thereof, a polyol-phosphate or sugar-phosphate salt and a plasticizer in the manufacture of a medicament for nasal, vaginal, rectal, oral mucosal, ophthalmic or ocular delivery.

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28. The use of a composition as defined in any one of claims 1 to 23 in the manufacture of a medicament for use in the transport of a therapeutic agent across a mucosal surface in an animal.

29. The use of a composition as defined in any one of claims 1 to 23 in the manufacture of a medicament for nasal, vaginal, rectal, oral mucosal, ophthalmic or ocular delivery.
- 5 30. The use according to any one of claims 26 to 29, wherein the medicament is intended for local action.
31. The use according to any one of claims 26 to 29, wherein the medicament is intended for systemic action.
- 10 32. The use of a composition as defined in any one of claims 1 to 23 in the administration of a therapeutic agent for transport thereof across a mucosal surface in an animal.
- 15 33. The use of a composition as defined in any one of claims 1 to 23 in nasal, vaginal, rectal, oral mucosal, ophthalmic or ocular delivery of a therapeutic agent to an animal.
- 20 34. The use according to claim 32 or 33, wherein the therapeutic agent is intended for local action.
35. The use according to claim 32 or 33, wherein the therapeutic agent is intended for systemic action.